K121885 P1/2

SEP 10 2012

510(K) SUMMARY
EarlySense Ltd.

EarlySense Central Display System (CDS)

Applicant's Name: EarlySense Ltd.
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Contact Person: Dalia Argaman
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Date Prepared: June 24, 2012

Trade Name: EarlySense Central Display Station

Classification Name: System Network and communication, physiological monitors (Product Code MSX)

Class: II

Regulation Number: 870.2300

Predicate Device: EverOn Central Display Station (CDS) (EarlySense Ltd); cleared under K110521

Device Description:
The EarlySense Central Display Station (CDS) is intended to communicate with multiple EarlySense Bedside monitoring devices and remotely display, on a central screen, the information as displayed on the individual Bedside monitoring units. The communication can be performed either via standard wired or via wireless LAN communication.

The transmitted information from Bedside to CDS includes alert information and physiological parameters. The CDS can also format the alert information as obtained from Bedside units into a message that can be transmitted to external devices that can communicate with the CDS via standard TCP/IP port. Data and report files (.CSV and

.PDF) generated at the Bedside units can be retrieved via the CDS by the user and can be downloaded and /or sent from the CDS. The CDS can also collectively generate, for all Bedside units connected to a CDS, unified tabulated reports that indicate the settings/alerts of each bedside unit.

The CDS includes standard hardware (PC, communication and IT hardware). EarlySense develops the application software which is used on the system's PC computer (Central Display Station), equipped with Linux Debian operating system.

Intended Use/ Indications for Use:
The EarlySense (EverOn) Central Display Station (CDS) is intended to provide secondary display of the information as displayed on multiple individual bed side monitoring units, on a central remote screen. The EarlySense (EverOn) CDS is not intended to replace any part of the bed-side patient monitoring procedures. The system can be used in hospitals or hospital type and clinic environment.

Substantial Equivalence
The EarlySense CDS on Linux operating system platform has the same technological characteristics, mode of operation, performance characteristics, and identical intended use and indications for use of its predicate device (K110521).

The operating system of the CDS was modified from Windows XP to Linux Debian. The modified CDS can also, display additional physiological parameters that might be displayed on EarlySense bedside unit (e.g., SpO_2). Additional reports displaying the settings/alerts from all connected Bedside units collectively, in tabulated format, are available. Additionally, minor GUI modifications for user convenience were performed.

Performance testing, inclusive of software verification and validation and Full load bench testing was performed to verify that all modifications introduced in the device as compared to its predicate device did not raise any new safety and effectiveness issues.

Based on the design verification and validation processes performed as a result of risk assessment and results of the testing performed, EarlySense Ltd. believes that the modified CDS is substantially equivalent to the cleared EverOn CDS without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 10 2012

EarlySense LTD.
Dalia Argaman
12 Tzvi St
Ramat Gan 52504, Israel

Re: K121885
EarlySense Central Display Station
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Monitor Network and Communication System
Regulatory Class: Class II
Product Code: MSX
Dated: August 7, 2012
Received: August 13, 2012

Dear Ms. Dalia Argaman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K121885

Device Name:

Indications For Use:

The EarlySense (EverOn) Central Display Station (CDS) is intended to provide secondary display of the information as displayed on multiple individual bed side monitoring units, on a central remote screen. The EarlySense (EverOn) CDS is not intended to replace any part of the bed-side patient monitoring procedures. The system can be used in hospitals or hospital type and clinic environment.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121885